BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Bacillus thuringiensis subsp. *israelensis* strain SUM-6218

Pesticide Chemical (PC) Code: 006642

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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I. EXECUTIVE SUMMARY

Background: In December 2011, Summit Chemical Company submitted an application for a new manufacturing-use pesticide product containing the active ingredient *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, at 100.00% concentration in powder form (EPA File Symbol 6218-IG), to the United States Environmental Protection Agency (EPA) under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Description of the Active Ingredient: L.H. Goldberg and J. Margalit originally isolated *Bacillus thuringiensis* subsp. *israelensis* (*Bti*) in Israel in 1977. *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 has a cream-like color and is a gram-positive, motile bacillus containing ellipsoid spores that readily stain with Coomassie Brilliant Blue. Cells grown on LB agar in the presence of 100 µg/mL penicillin show that the strain is penicillin resistant. Cells grown on modified egg yolk agar under anaerobic conditions develop white opaque zones of precipitation, indicating that they synthesize lecithinase. The delta endotoxins are insecticidal.

Assessing Risks to Human Health: Data derived from appropriate tests give no indication that the living microorganism is toxic or pathogenic to humans. No harmful health effects to humans are expected from the use of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 as a pesticide.

Assessing Risks to the Environment: Pesticide products containing *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 are not likely to pose a risk to the environment or to any nontarget organisms.

Public Participation: On October 1, 2009, the U.S. Environmental Protection Agency (EPA, or Agency) announced a policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this policy, EPA provides a public comment period prior to making a registration decision for the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; or any other registration actions for which EPA believes there may be significant public interest.

Consistent with the policy of making registration decisions more transparent, EPA's registration decision on a pesticide product containing the new active ingredient, *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, is subject to a concurrent 15-day comment period. While a final decision on registration is usually contingent upon review and consideration of public comments, the Agency believes that, based upon the risk assessment and information submitted in support of registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, it is in the best interest of the public and the environment to issue the registration for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 without delay. The basis for this decision can be found in the risk assessment for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, which is characterized throughout this Biopesticides Registration Action Document (BRAD) and the associated referenced documents. Although considered a new active ingredient by regulation, because the data and information supporting this new strain of *Bacillus thuringiensis* subsp. *israelensis* have established that it is substantially similar to previously registered *Bacillus thuringiensis* subsp. *israelensis* strains, the actual purpose for allowing pre-decisional public comments on new active ingredients is not served here. The following documents are being

made available for comment in the docket, identification number EPA-HQ-OPP-2012-0485, and accessed through either *http://www.regulations.gov* or *http://www.epa.gov/pesticides/regulating/registration-status.html*: (1) *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 Biopesticides Registration Action Document (BRAD); (2) label for the manufacturing-use pesticide product, Summit® Bti MP (EPA Registration Number 6218-83).

For definitions of scientific terms, please refer to *http://www.epa.gov/pesticides/glossary/*.

II. ACTIVE INGREDIENT OVERVIEW

Biological Name: *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218

Culture Collection: Deposited at the American Type Culture Collection (ATCC) in Manassas, Virginia under ATCC BAA-2453.

OPP Chemical Code: 006642

Type of Pesticide: Microbial Pesticide – Insecticide

See Appendix B for specific information (i.e., use sites, application rates, methods of application, formulation types, and target pests) regarding the pesticide product containing this active ingredient.

III. REGULATORY BACKGROUND

A. Applications for Pesticide Registration

On December 6, 2011, an application for registration was submitted on behalf of Summit Chemical Company, 235 South Kresson Street, Baltimore, MD 21224-2616 for the manufacturing-use pesticide product, Summit® Bti MP (EPA File Symbol 6218-IG), containing the new microbial active ingredient *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218. In the *Federal Register* of August 14, 2012 (77 FR 48520), EPA announced receipt of this application for registration of a pesticide product containing a new active ingredient for manufacturing use only. No comments were received following publication of this notice. For more information, see the following docket at *http://www.regulations.gov/*: EPA-HQ-OPP-2012-0485.

B. Food Tolerance Exemption

An exemption from the requirement of a tolerance is established for viable spores of the microorganism *Bacillus thuringiensis* Berliner in or on honey and honeycomb and all other raw agricultural commodities when it is applied either to growing crops, or when it is applied after harvest in accordance with good agricultural practices, provided the specifications set forth in the exemption are met (40 CFR 180.1011). The specifications are listed below:

(1) The microorganism shall be an authentic strain of *Bacillus thuringiensis* Berliner conforming to the morphological and biochemical characteristics of *Bacillus thuringiensis* as described in Bergey's Manual of Determinative Bacteriology, Eighth Edition.

(2) Spore preparations of *Bacillus thuringiensis* Berliner shall be produced by pure culture fermentation procedures with adequate control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.

(3) Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of five laboratory test mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.

(4) Spore preparations shall be free of the *Bacillus thuringiensis* β-exotoxin when tested with the fly larvae toxicity test ("Microbial Control of Insects and Mites," R.P.M. Bond et al., p. 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a *Bacillus thuringiensis* strain which does not produce β-exotoxin under standard manufacturing conditions or by periodically determining that β-exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.

Bacillus thuringiensis subsp. *israelensis* strain SUM-6218 meets the criteria of 40 CFR 180.1011.

IV. RISK ASSESSMENT

A. Product Analysis Assessment (40 CFR § 158.2120)

Microbial pesticide product analysis data requirements[1] include product chemistry and composition, analysis and certified limits, and physical and chemical characteristics data. Product chemistry and composition data include information about the identity of the active ingredient, the manufacturing process, deposition of a sample of the microbial active ingredient in a nationally recognized culture collection, and discussion of the potential for formation of unintentional ingredients. Analysis and certified limits data include information on analysis of samples and certification of limits. Physical and chemical characteristics data describe basic characteristics of the registered pesticide products, including color, physical state, odor, stability, miscibility, pH, corrosion characteristics, viscosity and density.

Bacillus thuringiensis subsp. *israelensis* strain SUM-6218 contained in Summit® Bti MP is a gram-positive, motile bacillus containing ellipsoid spores that readily stain with Coomassie

[1] For information on microbial data requirements, refer to *http://www.epa.gov/fedrgstr/EPA-PEST/2007/October/Day-26/p20828.htm*.

Brilliant Blue. Cells grown on LB agar in the presence of 100 µg/mL penicillin show that the strain is penicillin resistant. Cells grown on modified egg yolk agar under anaerobic conditions develop white opaque zones of precipitation, indicating that they synthesize lecithinase. The delta endotoxins are insecticidal. A sample of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 is deposited at the American Type Culture Collection (ATCC) in Manassas, Virginia under ATCC BAA-2453.

A new, unique PC code 006642 has been assigned to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, as it is a new active ingredient.

Refer to Table 1 in Appendix A for a summary of product chemistry and composition, analysis and certified limits data. Refer to Table 2 in Appendix A for a summary of physical and chemical characteristics data.

All product analysis data requirements required for registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 have been fulfilled.

B. Human Health Risk Assessment (40 CFR 158.2140)

1. Toxicity

All toxicology data requirements for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 have been fulfilled. Acceptable Tier I mammalian toxicology data and information support the registration of the pesticide product. Tier II and Tier III studies were not required. The results of the submitted studies are summarized below; for more information, refer to Table 3 in Appendix A.

a. Acute Toxicity/Pathogenicity – Tier I

In lieu of certain toxicology testing of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, the applicant provided acceptable scientific justifications/rationales to address the following data requirements, as described in more detail below. EPA generally agrees with the rationales provided (U.S. EPA 2012c).

Acute Oral Toxicity/Pathogenicity – Rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No). 48682610

Acute Pulmonary Toxicity/Pathogenicity – Rat (Harmonized Guideline 885.3150; MRID No. 48682611)

Cell Culture (Harmonized Guideline 885.3500; MRID No. 48682614): This study is not required because *Bacillus thuringiensis*, subsp. *israelensis* strain SUM-6218 is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).

Acute Oral Toxicity – Rat (Harmonized Guideline 870.1100; MRID No. 48682615)

Acute Dermal Toxicity – Rat (Harmonized Guideline 870.1200; MRID No. 48682616)

Acute Inhalation Toxicity – Rat (Harmonized Guideline 870.1300; MRID No. 48682617)

Primary Eye Irritation – Rabbit (Harmonized Guideline 870.2400; MRID No. 48682618)

Primary Dermal Irritation – Rabbit (Harmonized Guideline 870.2500; MRID No. 48682619)

Hypersensitivity Incidents (Harmonized Guideline 885.3400; MRID No. 48682613): EPA regulations require that hypersensitivity incidents, including immediate-type and delayed-type reactions of humans and domestic animals, that occur during the testing or production of the technical grade of the active ingredient, or manufacturing-use product, or end-use product, or are otherwise known to the applicant, be reported if they occur (refer to test note #3 of 40 CFR § 158.2140(d)). The applicant knows of no reports of hypersensitivity from *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

In lieu of testing *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, the applicant provided the following rationales to address the data requirements listed above:

1. Summit Chemical Company's *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 product is a manufacturing-use product intended for formulation into end-use products that are not meant to be applied to agricultural food, feed, or livestock, with the possible exception that livestock may drink water treated with *Bti* end-use products intended for mosquito larvae control. *Bti* end-use products may be used to control pest Diptera larvae that infest mushroom culture.

2. The manufacturing-use product consists of 100.00% *Bacillus thuringiensis* subsp. *israelensis,* and does not contain any inert ingredients likely to pose any significant human health risks.

3. The applicant claims that these studies are only required for registration of a microbial pesticide when the following conditions apply: The potential to cause adverse human health effects or the product characterization indicates the microbial pesticide has a significant potential to produce a mammalian toxin. While this is not exactly accurate per 40 CFR 158 subpart U, EPA agrees that in the case of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, there is very little potential for this active ingredient to cause adverse health effects. As described in the 1998 EPA Reregistration Eligibility Decision (RED) for *Bacillus thuringiensis,* (U.S. EPA 1998; hereafter referred to as the "*Bt* RED") toxicity testing conducted with other registered strains of *Bti* indicated no significant adverse effects to human health.

4. Toxicity/pathogenicity studies involving *Bacillus thuringiensis*-based pesticides have demonstrated no known mammalian health effects. The sum total of all toxicology data submitted to the Agency, complete with the lack of any reports of significant human health hazards of the various *Bacillus thuringiensis* strains, allow the conclusion that all toxicity studies may be waived as long as product identity and manufacturing process testing data indicate no mammalian toxicity associated with the strains.

Summit Chemical Company submitted the following toxicology study in support of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

Acute Injection Toxicity/Pathogenicity (Intravenous) – Rat (Harmonized Guideline 885.3200; MRID No. 48682612, 48954203): All animals survived, gained weight, and appeared normal during the study. No observable abnormalities were noted in any animal at necropsy. Kidney weight of both males and females was significantly decreased relative to untreated controls in *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218-treated animals, and brain and liver weight were significantly decreased in treated males. No test organism was detected in the brain tissue of the treated animals in group 3, and the test organism was cleared from the blood and kidneys by day 7. Test organism counts were near zero in the lungs from days 7 through 21. The test organism was not cleared from the liver, spleen, mesenteric lymph nodes, or caecum contents within the 21 days of the study. The caecum count peaked at day 7 (4.5×10^3) and decreased thereafter. The CFU count in the liver increased between days 3 and 7 and remained fairly steady thereafter. Test organism counts in the spleen declined through day 7 but increased thereafter, reaching 6.3×10^2 cfu/mL by day 21, while test organism counts in the mesenteric lymph nodes declined to 0 cfu/mL by day 14 and then increased to 2.4×10^2 cfu/mL by day 21. Acceptable clearance trends were demonstrated for all respective tissues. *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218does not appear to be toxic, infective or pathogenic in rats when dosed intravenously at 3.4×10^7 cfu/animal. These data were found acceptable.

b. Acute Toxicology and Subchronic Toxicity/Pathogenicity – Tier II; Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and Infectivity/Pathogenicity Analysis – Tier III

Tier II and Tier III studies were not required for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, based on the lack of acute toxicity/pathogenicity in the Tier I studies.

c. Endocrine Disruptors

As required by the Administrator under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) and has begun to implement the screening program that is to be used to test all pesticides to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." FFDCA section 408(p)(4), authorizes the Administrator, by order, to exempt from the requirements of the Endocrine Disruptor Screening Program a biologic substance or other substance if a determination is made that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contain 58 pesticide active ingredients and nine inert ingredients. *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP.

The Agency believes that *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 likely is a substance that would not produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance. As such, and pursuant to Section 408(p)(4), EPA will determine in the future whether it can exempt *Bacillus thuringiensis* subsp. *israelensis* strain

SUM-6218 from the requirements of the Section 408(p) EDSP. In the event the Agency does determine to exempt this substance from the EDSP, an order will be issued. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: *http://www.epa.gov/endo/*.

2. Occupational Exposure and Risk Characterization

The available data (e.g., lack of toxicity noted for oral, dermal, and inhalation routes of exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 do not demonstrate toxic potential to persons occupationally exposed to this microbial pest control agent. Standard personal protective equipment (PPE) on the label (mixer and handler use of an N-95 equivalent respirator) further mitigates unintentional exposures to formulators.

3. Human Health Risk Characterization

EPA considered human exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 in light of the standard for registration in FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result when the *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 manufacturing-use pesticide product is used to formulate end-use pesticide products in accordance with EPA-accepted labeling.

C. Environmental Assessment (40 CFR § 158.2150)

1. Ecological Hazards

In the *Bt* RED, EPA concluded that risks to nontarget organisms exposed to *Bacillus thuringiensis* (including *Bti*) are unlikely as long as the presence of heat labile exotoxins or beta-exotoxins is minimized. In addition to information submitted to show that beta-exotoxins will not be produced (U.S. EPA. 2012c), Summit Chemical Company provided EPA with an acceptable 21-day study on *Daphnia* (MRID 48682624, with supplemental information in MRIDs 48954200 and 48954201) to show that *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 does not produce heat-labile exotoxins. This study is summarized below and more fully described in the attached DER, and provides a satisfactory basis to make similar conclusions about *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 that have been made for other *Bti* based pesticides.

Summit Chemical Company also showed that *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 is substantially similar to the *Bti* originally isolated by Goldberg and Margalit and registered with EPA. Therefore, bridging to previously submitted data and extending conclusions on nontarget organisms from the *Bt* RED to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 are both possible. This was the applicant's approach to addressing the data requirements. In addition to citing EPA's conclusions, Summit Chemical Company cited specific data and other information to show that adverse effects on nontarget organisms are not expected as a result of

the registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218. The data and rationales submitted to support the nontarget risk assessment are described below.

The data and other information presented are sufficient to fulfill the relevant microbial pesticide data requirements for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 and for risk assessment purposes. Further testing of nontarget organisms at higher tier levels (i.e., Tiers II, III, and IV) is not required. EPA performed an environmental risk assessment, and has determined that adverse effects to nontarget organisms are not anticipated from the pesticidal uses of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218. Moreover, EPA has made a "No Effect" determination for direct and indirect effects to listed species and their designated critical habitats resulting from the registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 in a manufacturing use product.

For a summary of the generic data requirements described in sections IV(C)(1), refer to Table 4 in Appendix A.

a. Terrestrial Animals and Plants

Avian Oral and Avian Inhalation Toxicity (Harmonized Guidelines 885.4050 and 885.4100) (MRID Nos. 48682620 and 48682621): Results of previously submitted studies show that *Bti* was practically nontoxic to birds at 3.1 g/kg/day and 5 ml/kg/day to Northern bobwhite (*Colinus virginianus*) and mallard (*Anas platyrhynchos*) in avian oral studies (MRIDs 41842702, 41439006, and 41842703). Based on the available information, adverse effects to birds are not expected from exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

Wild Mammals Toxicity/Pathogenicity(Harmonized Guideline 885.4150) (MRID No. 48682622): Summit Chemical Company cited mammalian toxicity/pathogenicity data submitted previously to support registrations of *Bti*, including Accession Nos./MRIDs 142733, 41046704, 42006502, 43186101, 40951102, 96520, 96527, 96533, 109492, and 246968. Details of the findings of these studies are presented in the *Bt* RED. EPA also concluded in the *Bt* RED that infectivity/pathogenicity studies with *Bacillus thuringiensis* have demonstrated no known mammalian health effects. Additionally, Summit Chemical Company submitted an Acute Injection Toxicity/Pathogenicity study and additional rationales to satisfy toxicology data requirements to support the human health risk assessment (U.S. EPA. 2012c.), and EPA has no reason to believe that studies with laboratory animals would not be representative of potential effects on wild mammals. Therefore, based on the rationales, studies cited, and the study submitted, EPA does not expect that exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 will result in adverse effects to wild mammals.

Nontarget Insect and Honey Bee Testing (Harmonized Guidelines 885.4340 and 885.4380) (MRID Nos.48682627 and 48682628): Summit Chemical Company provided rationales as well as data citations to fulfill these data requirements. Summit referenced EPA's conclusions for nontarget insects and honey bees in the *Bt* RED, and noted that insect testing was not required (except for honey bee) because *Bt* functions by a toxic mode of action and does not cause epizootics in the field. Additionally, they cite previously submitted data on *Bti*. Under Guideline 885.4340, studies showed that *Bacillus thuringiensis* subsp. *israelensis* has a 16-day LC_{50} > 1.5 x

10 and 16-day NOEL = 2.5 x 10^4 cfu/g for the green lacewing; 30-day LC_{50} > 7.9 x 10^7 cfu/g diet for parasitic hymenoptera; 9-day LC_{50} > 1.8 x 10^8 cfu/g diet for a predaceous coleopteran; and 5-day LC_{50} > 7.0 x 10^7 cfu/g diet for honey bees (MRID 41842708, 41842709, 41842710, and 41842711).

While certain subspecies of *Bt* have shown adverse effects on honey bees, previously submitted tests with *Bti* on honey bees demonstrated minimal toxicity, according to the *Bt* RED. Additionally, studies submitted under Guideline 885.4380 showed that *Bacillus thuringiensis* subsp. *israelensis* has a 5-day LC_{50} > 7.0 x 10^7 cfu/g diet for honey bees (MRID 41842711).

Based on the data and other information submitted and cited, EPA does not anticipate that exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 will result in adverse effects to honey bees and other nontarget insects.

Nontarget Plant Testing (Harmonized Guideline 885.4300); (MRID No. 48682626): EPA requires nontarget plant testing only when the active ingredient is taxonomically related to known plant pathogens. *Bti* is not a plant pathogen and is not related to known plant pathogens, so testing on nontarget plants is not required. EPA does not anticipate adverse effects to nontarget plants as a result of exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

b. Aquatic Animals and Plants

Freshwater Fish Toxicity/Pathogenicity (Harmonized Guideline 885.4200) (MRID No. 48682623): Summit Chemical Company cited previously submitted data in addition to rationales citing previous conclusions on the currently registered *Bti*. Studies submitted in accordance with Guideline 885.4200 (Freshwater Fish Toxicity) showed that *Bti* have aqueous LC_{50}s of > 8.7 x 10^9 cfu/L and 1.4 x 10^{10} cfu/L and oral LC_{50}s of > 1.7 x 10^{10} cfu/g food and > 5.3 x 10^9 cfu/g food in rainbow trout. Studies with bluegill sunfish determined aqueous LC_{50}s of > 8.9 x 10^9 cfu/L and LC_{50} > 1.6 x 10^{10} cfu/L and oral LC_{50}s of > 1.3 x 10^{10} cfu/g food and > 4.3 x 10^9 cfu/g food (MRIDs 41439008, 41980105, 41439007, 41842704). Based on this information, EPA concludes that adverse effects to freshwater fish are unlikely to result from exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

Freshwater Invertebrate Toxicity/Pathogenicity (Harmonized Guideline 885.4240) (MRID No. 48682624, 48954201*):* Summit Chemical Company submitted a 21-day study with *Daphnia magna* to demonstrate the effects of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 on freshwater invertebrates. The LC_{50} was determined to be > 1.0 x 10^3 cfu/mL. It is noted also that no effects on survival were observed at the two highest concentrations tested (1.0 x 10^5 and 1.0 x 10^6 cfu/mL). The NOEC and LOEC based on reproduction are 1.0 x 10^6 and > 1.0 x 10^6 cfu/mL, respectively. The NOEC and LOEC based on mass of surviving adults are 1.0 x 10^3 and 1.0 x 10^4 cfu/mL, respectively; however, the study reviewer noted that the effect observed was an increase in body weight, which is not considered deleterious in this case. The study is sufficient to demonstrate that *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 does not cause detrimental effects to freshwater invertebrates and also does not product heat labile exotoxins.

Estuarine/Marine Fish and Invertebrate Testing (Harmonized Guideline 885.4280), (MRID No. 48682625): Summit Chemical Company cited data submitted previously on estuarine/marine fish and invertebrates. Studies submitted according to Guideline 885.4280 showed that *Bacillus thuringiensis* subsp. *israelensis* has NOELs of $> 2.0 \times 10^{10}$ cfu/g and NOEL $> 4.2 \times 10^{9}$ cfu/g food for grass shrimp; an oral NOEL $> 2.0 \times 10^{10}$ cfu/g food and oral and aqueous LC_{50}s of $> 2 \times 10^{10}$ cfu/g food and $LC_{50} > 7.2 \times 10^{9}$ cfu/L, respectively, for sheepshead minnow; and a NOEL = 50 mg/kg sediment for a marine copepod (MRIDs 41540402, 41842706, 41540401, 41842707, and 41439010). This information is sufficient to conclude that adverse effects to estuarine/marine fish and invertebrates resulting from exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 are unlikely.

2. Environmental Fate Assessment Data

Environmental fate and groundwater data requirements (Tier II testing) were not triggered because there were no significant adverse effects to nontarget organisms in the Tier I toxicity studies cited or submitted, and because acceptable rationales address certain nontarget organism data requirements not fulfilled by testing (as discussed in C.1. above and summarized in Table 4, Appendix A). Additionally, the product is only registered for manufacturing use, which limits environmental exposure.

3. Ecological Exposure and Risk Characterization

Since the product is registered for manufacturing use only, exposure to nontarget organisms is not anticipated. Based on this expected lack of exposure and the data/information discussed above, EPA concludes that risks to nontarget organisms are minimal as a result of registering *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

Additional consideration for nontarget exposure and a risk assessment may be necessary if an end use product containing *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 is proposed for registration.

4. Endangered Species Assessment

Since EPA has determined that no effects are anticipated for nontarget species exposed to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 as a result of its labeled use, effects to federally listed threatened and endangered species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to federally listed threatened and endangered species and their designated critical habitats for the use of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, as labeled.

V. ENVIRONMENTAL JUSTICE

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair

treatment means that no group of people, including racial, ethnic, or socioeconomic groups, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local, and tribal environmental programs and policies. Meaningful involvement means that (1) potentially affected community residents have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public's contribution can influence the regulatory agency's decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the decision-makers seek out and facilitate the involvement of those potentially affected. EPA has this goal for all communities and persons across the U.S.

To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result their location, cultural practices, or other factors, may have atypical, unusually high exposure to *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218, compared to the general population. Please comment if you are aware of any subpopulations that may have atypical, unusually high exposure compared to the general population.

For additional information regarding environmental justice issues, please visit EPA's web site at *http://www.epa.gov/compliance/environmentaljustice/index.html*.

VI. RISK MANAGEMENT DECISION

Section 3(c)(5) of FIFRA provides for the registration of a pesticide provided that all the following determinations are made: (1) its composition is such as to warrant the claims for it; (2) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (3) it will perform its intended function without unreasonable adverse effects on the environment; and (4) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion (1), the composition of the *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 pesticide product has well-known properties. EPA has no knowledge that would contradict the claims made on the label for the manufacturing-use pesticide product, Summit® Bti MP, and the pesticide product is not expected to cause unreasonable adverse effects on the environment when used according to the label instructions. Criterion (2) is satisfied by the current product label, as well as the data and information presented in this document. EPA believes that the *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 pesticide manufacturing-use product, if used to formulate registered microbial end-use pesticide products, will not cause any unreasonable adverse effects on the environment, and such end-use products are likely to control pests, satisfying criterion (3). Criterion (4) is satisfied in that the *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 manufacturing–use pesticide product is not expected to cause unreasonable adverse effects when used according to label instructions. Therefore, Summit® Bti MP, containing *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 as a new active ingredient, is eligible for registration under FIFRA section 3(c)(5) for the labeled uses.

VII. ACTIONS REQUIRED OF THE REGISTRANT

A. Final Printed Labeling

Before releasing the pesticide product containing *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 for shipment, the registrant is required to provide appropriate final printed labeling to EPA.

B. Terms of Registration

As a term of the registration, the applicant must submit the results of storage stability testing (Harmonized Guideline 830.6317) within one year of registration.

C. Reporting of Adverse Effects and Hypersensitivity Incidents

Notwithstanding the information stated in the previous sections, it should be clearly understood that certain specific data are required to be reported to EPA as a requirement for maintaining the federal registration for a pesticide product. A brief summary of these types of data are listed below.

> Reports of all incidents of adverse effects to the environment must be submitted to EPA under the provisions stated in FIFRA section 6(a)(2). Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to EPA under the provisions of 40 CFR § 158.2140(d).

VIII. BIBLIOGRAPHY

For definitions of scientific terms, please refer to *http://www.epa.gov/pesticides/glossary/*.

A. Studies Submitted to Support the Registration of Pesticide Product Containing *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218.

MRID	Citation	Date
48682600	Summit Chemical Company (2011) Submission of Product Chemistry, Toxicity and Exposure and Risk Data in Support of the Application for Registration of Bacillus thuringiensis subsp. israelensis (Bti) TGAI/MUP/MP/PP. Transmittal of 29 Studies.	08-Dec-2011
48682601	Borovsky, D. (2010) Product Identity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by University of Florida-IFAS. 16p.	08-Dec-2011
48682602	Benzon, G.; Finkenbinder, C. (2011) Product Identity (Bioassay Analysis/Identity/Characterization) of Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Benzon Research. 16p.	08-Dec-2011
48682603	Rose, R. (2011) Manufacturing Process for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 6p.	08-Dec-2011
48682604	Rose, R. (2011) Deposition of a Sample in a Nationally Recognized Culture Collection of Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682605	Rose, R. (2011) Discussion of Formation of Unintentional Ingredients for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682606	Benzon, G.; Finkenbinder, C. (2011) Analysis of Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Benzon Research. 21p.	08-Dec-2011
48682607	Rose, R. (2011) Certification of Limits for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 2p.	08-Dec-2011
48682608	Rose, R. (2011) Physical and Chemical Properties for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 12p.	08-Dec-2011
48682609	Rose, R. (2011) Residue Data for Tolerance Exemption for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 4p.	08-Dec-2011
48682610	Rose, R. (2011) Acute Oral Toxicity/Pathogenicity (TGAI) for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682611	Rose, R. (2011) Acute Pulmonary Toxicity/Pathogenicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682612	Monds, K. (2011) Bacillus thuringiensis subsp./var. israelensis Strain SUM-6218, Primary Powder/MUP/TGAI: Acute Injection Toxicity/Infectivity Study in Rats: Final Report. Project Number: 14546/10. Unpublished study prepared by Stillmeadow, Inc. 29p.	08-Dec-2011
48682613	Rose, R. (2011) Hypersensitivity Incidents for Summit's Bacillus thuringiensis subsp.	08-Dec-2011

	israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 2p.	
48682614	Rose, R. (2011) Cell Culture for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 2p.	08-Dec-2011
48682615	Rose, R. (2011) Acute Oral Toxicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682616	Rose, R. (2011) Acute Dermal Toxicity for Summit's Bacillus Thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 4p.	08-Dec-2011
48682617	Rose, R. (2011) Acute Inhalation Toxicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682618	Rose, R. (2011) Acute Eye Irritation for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682619	Rose, R. (2011) Primary/Acute Dermal Irritation for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682620	Rose, R. (2011) Avian Oral Toxicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 4p.	08-Dec-2011
48682621	Rose, R. (2011) Avian Inhalation Toxicity/Pathogenicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 4p.	08-Dec-2011
48682622	Rose, R. (2011) Wild Mammal Toxicity/Pathogenicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 4p.	08-Dec-2011
48682623	Rose, R. (2011) Freshwater Fish Toxicity/Pathogenicity for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682624	Brunner, S. (2011) Bacillus thuringiensis subsp./var. israelensis, Strain: Sum-6218, Primary Powder/MUP/TGAI: MPCA Freshwater Aquatic Invertebrate Test with Daphnia magna: Final Report. Project Number: 14472/10. Unpublished study prepared by Stillmeadow, Inc. 33p.	08-Dec-2011
48682625	Rose, R. (2011) Estuarine and Marine Fish and Invertebrate Testing for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682626	Rose, R. (2011) Nontarget Plant Testing for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit CHemical Co. 3p.	08-Dec-2011
48682627	Rose, R. (2011) Nontarget Insect Testing for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682628	Rose, R. (2011) Honeybee Testing for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 3p.	08-Dec-2011
48682629	Rose, R. (2011) Threatened and Endangered Species Analysis for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Summit Chemical Co. 4p.	08-Dec-2011
48954200	Summit Chemical Company (2012) Submission of Toxicity Data in Support of the Application for Registration of Summit Bti MP. Transmittal of 4 Studies.	28-Sep-2012
48954201	Rodrigue, N. (2010) Analytical Report: Semiannual Tap, Fresh, & Salt Water. Unpublished study prepared by Test America, Inc. 60p.	28-Sep-2012

48954202	Doig, A. (2012) Each Lot of Spore Preparation, Prior to the Addition of Other Materials, Shall be Tested by Subcutaneous Injection of at Least 1 Million Spores Into Each of Five Laboratory Test Mice for Summit"s Bacillus thuringiensis subsp. israelensis (Bti) MP. Project Number: 16557/12. Unpublished study prepared by Stillmeadow, Inc. 4p.	28-Sep-2012
48954203	Monds, K. (2012) Bacillus thuringiensis subsp./var. israelensis Strain SUM-6218, Primary Poweder/MUP/TGAI: Amended Final Report. Project Number: 14546/10. Unpublished study prepared by Stillmeadow, Inc. 34p.	28-Sep-2012
48954204	Thomas, J.; Barrow, S. (2011) Pre- and Post-Toxicity CFU Analysis. Project Number: 14577/10. Unpublished study prepared by Stillmeadow, Inc. 3p.	28-Sep-2012
49032000	Summit Chemical Company (2012) Submission of Product Chemistry Data in Support of the Application for Registration of Bti MP. Transmittal of 1 Study.	21-Dec-2012
49032001	Rose, R. (2011) Manufacturing Process for Summit's Bacillus thuringiensis subsp. israelensis (Bti) MP. Unpublished study prepared by Robert Rose. 6p.	21-Dec-2012
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B. Environmental Protection Agency Risk Assessment Memoranda

U.S. EPA. 2013a. Environmental risk assessment for the FIFRA Section 3 registration of *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218. Memorandum from S.Borges to D. Greenway dated April 17, 2013.

U.S. EPA. 2012e. Review of the Registrant’s response to the deficiencies found by the Agency in its review of product chemistry, manufacturing process for the registration of the TGAI *Bt. israelensis* strain SUM-6218.Memorandum from I. S. Barsoum to D. Greenway dated March 12, 2013.

U.S. EPA. 2012a. Review of the Registrant’s Response to the Deficiencies found by the Agency in its review of the Freshwater Aquatic Invertebrate Test with *Daphnia Magna* study… Memorandum from A. Waggoner to D. Greenway dated December 10, 2012.

U.S. EPA. 2012b. Review of the Registrant's response to the deficiencies found by the Agency in its review of product chemistry, manufacturing process, and acute toxicity studies for the registration of the TGAI *Bt. israelensis* strain SUM-6218. Memorandum from I. S. Barsoum to D. Greenway dated November 13, 2012.

U.S. EPA. 2012c. Review of Product Chemistry, Acute Injection Tox/Path study, and waiver request for Toxicity data requirements for section 3 registration of the TGAI: *Bacillus thuringiensis israelensis* strain SUM-6218. Memorandum from I. S. Barsoum to D. Greenway dated July 10, 2012.

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APPENDIX A. MICROBIAL PESTICIDES DATA REQUIREMENTS (40 CFR PART 158 – SUBPART V)

TABLE 1. Product Analysis Data Requirements for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (40 CFR § 158.2120)

Harmonized Guideline Number	Data Requirement	Results Summary	MRID No.
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. Summit® Bti MP contains 100.00% by weight *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218	48682601 48682603 48682606 48682607 48682608 49054001
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.	
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	
N/A	Deposition of a Sample in a Nationally Recognized Culture Collection	A sample of *Bacillus thuringiensis* subsp. ***israelensis*** strain SUM-6218is on deposit with the American Type Culture Collection under Accession Number ATCC BAA-2453	
885.1400	Analysis of Samples	As a term of Summit® Bti MP manufacturing-use product registration, EPA is requiring submission of a storage stability study within one year of registration.	
885.1500	Certification of Limits	Limits are adequate/acceptable.	

TABLE 2. Physical and Chemical Characteristics for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (40 CFR § 158.2120)	
Guideline Reference No./Property	**Description of Results**
830.6302 Color	Light brown, beige, or tan
830.6303 Physical State	Flour-like powder
830.6304 Odor	Mild, earthy, slightly yeast-like
830.6313 Stability	The product is coagulated or deactivated at elevated temperatures. The product will not be exposed to elevated temperatures, metals, or metal ions during storage and intended use. It is stored in PE-lined fiberboard drums.
830.6314 Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain oxidizing or reducing ingredients.
830.6315 Flammability	Not applicable, the product is a powder.
830.6316 Explodability	Not applicable, the product does not contain explosive ingredients.
830.6317 Storage Stability	No physical or chemical change observed when stored under warehouse conditions for at least two years. The registrant has manufactured mosquito dunks and briquets using another brand of Bti MP stored as long with no change in potency of those products.
830.6319 Miscibility	Not applicable, the product is not to be diluted with nonpolar solvents.
830.6320 Corrosion Characteristics	Non-corrosive to metals, glass, or various plastics such as polyethylene or polyvinyl alcohol.
830.6321 Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment.
830.7000 pH	Not applicable, the product is a solid.
830.7100 Viscosity	Not applicable, the product is a solid.
830.7200 Melting Range	Not applicable, the product is composed of spores and fermentation media.
830.7220 Boiling Range	Not applicable, the product is a solid.
830.7300 Density/Relative Density/Bulk Density	0.4 to 0.56 depending on degree of compaction or settling 25-35 lb/ft^3
830.7370 Dissociation Constant in Water	Not applicable, the product forms a fine-particulate suspension in water that settles out over time and easily redistributes in the water column when mildly agitated.
830.7550 Partition Coefficient	Not applicable, the product is a solid.
830.7840 Water Solubility	Not applicable, the product forms a fine-particulate suspension in water that settles out over time and easily redistributes in the water column when mildly agitated.
830.7950 Vapor Pressure	Not applicable, the product is not volatile.

[a]Data from MRID 48682608

TABLE 3. Tier I Toxicology Data Requirements for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (40 CFR § 158.2140)			
Harmonized Guideline Number	**Data Requirement**	**Results Summary and Classification**	**MRID No.**
885.3050	Acute Oral Toxicity/ Pathogenicity	Waived	48682610
885.3150	Acute Pulmonary Toxicity/ Pathogenicity	Waived	48682611
885.3200	Acute Injection Toxicity/ Pathogenicity (Intravenous)	Summit® Bti MP does not appear to be toxic or pathogenic in rats when dosed intravenously at 3.4 x 10^7 cfu/animal. Classification: Acceptable Spore Preparation (Supplemental) Amended Final Report (Supplemental) Pre/Post-toxicity CFU analysis (Acceptable)	48682612 48954202 48954203 48954204
885.3400	Hypersensitivity Incidents	EPA regulations require that hypersensitivity incidents, including immediate-type and delayed-type reactions of humans and domestic animals, that occur during the testing or production of the technical grade of the active ingredient, or manufacturing-use product, or end-use product, or are otherwise known to the applicant, be reported if they occur (refer to test note #3 of 40 CFR § 158.2140(d)). There are no reports of hypersensitivity from *Bacillus thuringiensis*, subsp. *israelensis* strain SUM-6218 known to the applicant.	48682613
885.3500	Cell Culture	Not required because *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).	48682614
870.1100	Acute Oral Toxicity	Waived TOXICITY CATEGORY III	48682615
870.1200	Acute Dermal Toxicity	Waived TOXICITY CATEGORY III	48682616
870.1300	Acute Inhalation Toxicity	Waived TOXICITY CATEGORY III	48682617
870.2400	Acute Eye Irritation	Waived TOXICITY CATEGORY III	48682618
870.2500	Primary Dermal Irritation	Waived TOXICITY CATEGORY III	48682619

[1] According to 40 CFR § 158.2120, these data are only required for the technical grade of the active ingredient.

Table 4. Non-target Organism Toxicity Requirements for *Bacillus thuringiensis* subsp. *israelensis* strain SUM-6218 (40 CFR 158.2150)			
Harmonized Guideline Number	**Data Requirement**	**Results Summary and Classification**	**MRID No.**
885.4050	Avian oral toxicity/pathogenicity	Rationales and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41842702, 41439006, and 41842703 **Classification: Acceptable**	48682620
885.4100	Avian inhalation toxicity/pathogenicity	Rationales and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41842702, 41439006, and 41842703 **Classification: Acceptable**	48682621
885.4150	Wild mammal toxicity/pathogenicity	Rationales and studies cited are sufficient to satisfy the data requirement. Cited Accession Nos./MRIDs: 142733, 41046704, 42006502, 43186101, 40951102, 96520, 96527, 96533, 109492, and 246968 **Classification: Acceptable**	48682622
885.4200	Freshwater fish toxicity/pathogenicity	Rationales and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41439008, 41980105, 41439007, and 41842704 **Classification: Acceptable**	48682623
885.4240	Freshwater invertebrate toxicity/pathogenicity	A 21-day study shows that the EC_{50} to *Daphnia magna* based on mortality/immobility is > 1.0×10^3 CFU/mL, the NOEC based on reproduction was 1.0×10^6 CFU/mL, and the NOEC based on body weight was 1.0×10^3 CFU/mL (though, effect was weight gain not loss). Study is sufficient to show that heat labile exotoxins are not produced. **Classification: Acceptable** A semiannual analytical reporting of tap, fresh and salt water. **Classification: Supplemental**	48682624 48954201
885.4280	Estuarine/marine fish and invertebrate testing	Rationales and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41540402, 41842706, 41540401, 41842707, and 41439010 **Classification: Acceptable**	48682625
885.4300	Nontarget plant testing	Rationales submitted was sufficient to determine that adverse effects are not expected in plants as a result of exposure to *Bti* SUM-6218. **Classification: Acceptable**	48682626
885.4340	Nontarget insect testing	Rationales and studies cited are sufficient to satisfy the data requirement. Cited MRIDs: 41842708, 41842709, 41842710, and 41842711 **Classification: Acceptable**	48682627
885.4380	Honey bee testing	Rationales and studies cited are sufficient to satisfy the data requirement. Cited MRID: 41842711 **Classification: Acceptable**	48682628
Non-guideline	Endangered Species Assessment	A summary of information was provided. These data are not required. **Classification: Supplemental**	48682629

APPENDIX B. PESTICIDE PRODUCT

EPA Registration Number	Product Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate	Target Pest(s)
6218-83	Summit® Bti MP	100.00%	Manufacturing-Use Product (powder)	For manufacturing use only	N/A	N/A	N/A